PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:

see form PCT/ISA/220

PCT

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

Date of mailing
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference
see form PCT/ISA/220

FOR FURTHER ACTION
See paragraph 2 below

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/JP2006/313444	29.06.2006	30.06.2005

International Patent Classification (IPC) or both national classification and IPC
INV. A61K31/202 A23L1/30 A61P25/24 A61P25/28 A61P43/00

Applicant
SUNTORY LIMITED

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☒ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notifed the International Bureau under Rule 66.1*bis*(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA:	Date of completion of this opinion	Authorized Officer
European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	see form PCT/ISA/210	RODRIGUEZ-PALMERO, M Telephone No. +49 89 2399-7871

Form (PCT/ISA/237) (Cover Sheet) (April 2005)

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/JP2006/313444

Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of:

   ☒ the international application in the language in which it was filed

   ☐ a translation of the international application into , which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1 (b)).

2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

   a. type of material:

      ☐ a sequence listing

      ☐ table(s) related to the sequence listing

   b. format of material:

      ☐ on paper

      ☐ in electronic form

   c. time of filing/furnishing:

      ☐ contained in the international application as filed.

      ☐ filed together with the international application in electronic form.

      ☐ furnished subsequently to this Authority for the purposes of search.

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of

☐ the entire international application

☒ claims Nos. 21 with respect of industrial applicability

because:

☒ the said international application, or the said claims Nos. 21 with respect of industrial applicability relate to the following subject matter which does not require an international search *(specify)*:

see separate sheet

☐ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. are so unclear that no meaningful opinion could be formed *(specify)*:

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed *(specify)*:

☐ no international search report has been established for the whole application or for said claims Nos.

☐ a meaningful opinion could not be formed without the sequence listing; the applicant did not, within the prescribed time limit:

☐ furnish a sequence listing on paper complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Searching Authority in a form and manner acceptable to it.

☐ furnish a sequence listing in electronic form complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Searching Authority in a form and manner acceptable to it.

☐ pay the required late furnishing fee for the furnishing of a sequence listing in response to an invitation under Rules 13*ter*.1(a) or (b).

☐ a meaningful opinion could not be formed without the tables related to the sequence listings; the applicant did not, within the prescribed time limit, furnish such tables in electronic form complying with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions, and such tables were not available to the International Searching Authority in a form and manner acceptable to it.

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in electronic form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.

☐ See Supplemental Box for further details

Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	-
	No:	Claims	1-22
Inventive step (IS)	Yes:	Claims	-
	No:	Claims	1-22
Industrial applicability (IA)	Yes:	Claims	1-20,22
	No:	Claims	-

2. Citations and explanations

see separate sheet

Re Item III

Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

Claim 21 relates to subject-matter considered by this Authority to be covered by the provisions of Rule 67.1(iv) PCT. Consequently, no opinion will be formulated with respect to the industrial applicability of the subject-matter of this claim (Article 34(4)(a)(I) PCT).

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. The following documents are referred to in this communication; the numbering will be adhered to in the rest of the procedure:

D1: WO 98/50052 A (INST RECH BIOLOG SA [FR]; PONROY YVES [CH]) 12 November 1998.
D2: WO 2004/084882 A (SUNTORY LTD [JP]; AKIMOTO KENGO [JP]; ONO YOSHIKO [JP]; KAWASHIMA HIRO) 7 October 2004.
D3: EP-A1-1 419 768 (SUNTORY LTD [JP]) 19 May 2004.
D4: WO 2004/028529 A (SUNTORY LTD [JP]; AKIMOTO KENGO [JP]; KOGA YOSHIHIKO [JP]) 8 April 2004.
D5: WO 02/02105 A (LAXDALE LTD [GB]; HORROBIN DAVID F [GB]) 10 January 2002.

1.1 Unless indicated, reference is made to the passages indicated in the international search report.

2. **Novelty (Art. 33(2) PCT)**

2.1 Present claims concern a composition comprising arachidonic acid and/or a compound having arachidonic acid as a constituent fatty acid for medicine (claims 1-19), a method of producing such a composition (claim 20), the use of said composition for ameliorating, preventing or treating a reduced amount of diurnal

activity and/or depressive symptoms (claim 21) and a food or drink comprising such a composition (claim 22).

2.2 The term "ameliorating, preventing or treating a reduced amount of diurnal activity" in the medical use claim 21 is not considered to be clear, since it does not allow any practical application in the form of a defined, real treatment of a pathological condition (disease) (Guidelines C-IV, 4.2).

For the purpose of the present communication, the passage on page 4 (lines 11-33) has been taken into consideration, for clarification of the meaning of the term mentioned above.

2.3 D1 discloses the use of phospholipids rich in arachidonic acid (AA) and docosahexaenoic acid for improving the quality of sleep, alertness during the day, memory and learning processes by regulating melatonin secretion. It is shown therein that the administration of AA reduces the number of episodes of sonmolence during the day and has a favourable effect on quality and duration of sleep as well as daily vigilance. Moreover, it mentions that it is particularly adequate for aged people or bad sleepers. Therefore, this document shows that the diurnal activity is increased with the AA consumption.

D2 shows that the use of AA as such, or as constituent of an alcohol ester, a triglyceride, a phospholipid or a glycolipid improves a biorhythm disorder, sleep disorder and delayed sleep phase syndrome.

D3 discloses the use of AA as such, or as constituent of an alcohol ester, a triglyceride, a phospholipid or a glycolipid for the treatment of depression and for prevent or ameliorate decreased cognitive ability. Furthermore, it mentions that such compositions are useful for ameliorating the decreased brain function accompanying aging (for diminishing forgetfulness, senility and increasing memory, concentration, attentiveness, refreshing mind, wakefulness and youth). All these properties are considered to fall into the term "ameliorating, preventing or treating a reduced amount of diurnal activity" as interpreted in the light of the description.

D4 teaches the use of AA as such, or as constituent of an alcohol ester, a triglyceride, a phospholipid or a glycolipid for improving normal responses of cognitive abilities of a healthy person.

D5 concerns the use of glycerides, esters or phospholipids comprising AA for the treatment of schizophrenia, depression, Alzheimer, dementia or Parkinson.

2.4 Therefore, the subject-matter of the composition claims 1-19 and 22 and method of production of said compositions (claim 20) are considered to be anticipated by the prior art documents of the international search report, in particular by D2-D4. The use of claim 21 is also considered to lack novelty in the light of D1-D5, since all these documents show increases of diurnal activity and/or treatment of depression with the administration of compositions comprising AA.

3. **Inventive Step (Art. 33(3) PCT)**

Claims 1-22 are not considered novel and therefore cannot be considered inventive over the prior art.

4. **Industrial applicability (Art. 33(4) PCT)**

4.1 For the assessment of the present claim 21 on the question whether it is industrially applicable, no unified criteria exist in the PCT Contracting States. The patentability can also be dependent upon the formulation of the claims. The EPO, for example, does not recognize as industrially applicable the subject-matter of claims to the use of a compound in medical treatment, but may allow, however, claims to a known compound for first use in medical treatment and the use of such a compound for the manufacture of a medicament for a new medical treatment.

4.2 Present claims 1-20 and 22 are susceptible of industrial application and thus do not contravene Art. 33(4) PCT.